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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/147,912 11/03/93 WAHL

G P419498

LOWE EXAMINER

18N2/0419

STEPHEN E. REITER
PRETTY, SCHROEDER, BRUEGGEMANN & CLARK
444 S. FLOWER ST., STE. 2000
LOS ANGELES, CA 90071

ART UNIT PAPER NUMBER

1804

DATE MAILED:

04/19/96

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BEFORE THE BOARD OF PATENT
APPEALS AND INTERFERENCES

PAPER NO.: 38

Examiner: Low
Art Unit: 1804

Application Serial Number: 08/147,912
 Filing Date: 3 November 1993
 Appellant(s): Wahl *et al.*

MAILED
APR 19 1996
GROUP 1800

Stephen E. Reiter
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's reply brief
on appeal filed on 16 February 1996

The reply brief filed 16 February 1996 has been entered and considered as follows but does not meet the criteria set forth in 37 C.F.R. 1.193(b) because there are no new grounds of rejection and no new points of argument. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

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Items II and III (reply brief page 2) are noted and are not new issues nor part of any ground of rejection. Items IV to VI (reply brief pages 2-6) represent the identical material already present in the appeal brief filed 2 October 1995 (pages 2-5). Item VIII of the reply brief indicates that the claim grouping remains as indicated in the appeal brief of 2 October 1995. As to the foregoing items II to VI and VIII, none are new issues and none are new point of argument and none are new rejections. The reply brief with regard to these items does not conform to the criteria of 37 C.F.R. 1.193(b).

In item VII. ISSUES, appellant states that issues 1-6 remain as indicated in the appeal brief (filed 2 October 1995) and adds what appellant calls issue 7 and asserts there is a new point of argument as to the second DNA recombining randomly in the genome at sites other than the FLP recombination site. In item IX. ARGUMENT, appellant discusses (1) an asserted new argument and (2) a disagreement as to insertion sites other than FLP and FRT and refers to page 3, lines 8-9 and 23-24 as well as page 5, lines 27-29.

As to the foregoing, it is not a new issue. It is appellant's brief filed 2 October 1995 in the first sentence of the paragraph bridging pages 6-7 that indicated "Integration of the initial FLP recombination target site is not targeted". Thus, it is applicant who raised the issue of random and multiple targets since the "Integration of the initial FLP recombination target site is not targeted" there is no indication in the claims that there is one and only one site that is present.

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As to the asserted new argument, this is not a new argument. This application is a File Wrapper Continuing application of 07/666,252. Thus, all communications to and communications from the United States Patent and Trademark Office are part of the file history of this application. In paper number 18 at page 2, the Office Action in part indicated that given these difficulties how is the non-human transgenic host organism which is any nonhuman organism such as a mammal or insect or

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invertebrate used in the process made so that the FLP target site is not at some random location and what gene is it located in? Before a specific gene can be targeted by DNA which contains the FLP recombination target site (FRT), it must have a specific site for recombination already in the genome of the host. Here, the specification has not indicated any particular transgenic animal where the location of the FLP sites are initially at specific sites predetermined by the user. Note that page 9, lines 10-14 refers to the non-human transgenic animal with the FLP site but does not indicate how the specificity of the placement of the site in the genome is determined or produced, i.e. how is the FLP site for the animal specifically targeted to a specific gene and what portions of that gene are best suited to or for integration of the FLP recombination site? Inasmuch as the non-human mammal contains cells *per se*, and the FLP site is in the cells, the specification has not provided enabling description for site specific integration of the DNA coding for the FLP site (i.e. the target for the DNA which recombines at the FLP site)". Thus, appellant's arguments are not persuasive nor directed to a new point of argument.

As to the argument regarding credible evidence, appellant's comments are not persuasive in light of appellant's own comments in the appeal brief filed 2 October 1995 as discussed above. It is also noted that appellant refers to page 12, lines 5-17 (and figure 1A and B) of the present application written description as support, however, (1) the claims on appeal are not direct to the specific constructs referred to on page 5 but to any construct and the present specification does not disclose at page 5 that all constructs are specific and is contradictory to appellant's statements in the brief filed 2 October 1995 in the first sentence of the paragraph bridging pages 6-7 that indicated "Integration of the initial FLP recombination target site is not targeted". Thus, the comments in appellant's reply brief are not persuasive.

For the reasons indicated in the examiner's answer (paper number 36) the above rejections should be affirmed and as indicated above the asserted new point of argument is not new. The reply brief does not meet the criteria set forth in 37 C.F.R. 1.193(b)

Respectfully,

Christopher Low
18 April 1996

Christopher S. F. Low
CHRISTOPHER S. F. LOW
PRIMARY EXAMINER
GROUP 1800